FEB - 5 2001

K 001781

V. 510(k) SUMMARY

Submitted by:	Neurosoft, Inc. 45150 Business Court, Suite 100 Sterling, VA 20166 Phone: (703) 904-9600 Fax: (703) 904-7870
Contact Person:	David B. Jones
Date Prepared:	June 9, 2000
Proprietary Name:	NEURO SCAN MEDICAL SYSTEMS' **CURRY® Multimodal Neuroimaging Software**
Common Name:	Electroencephalograph (EEG) Software
Classification Name:	Electroencephalograph (GWQ) Software (882.1400)
Predicate Device:	SAM Technology, Inc. "IMAGE VUE EEG" (K980477)
Device Description:	The CURRY® Multimodal Neuroimaging Software integrates multiple, complementary image modalities (EEG and/or MEG with MRI, fMRI, CT PET and/or SPECT) in a single software package for electromagnetic source localization and visualization.
Intended Use:	The Neurosoft CURRY® Multimodal Neuroimaging Software is intended for use by qualified/trained EEG technologists and/or physicians on both adult and pediatric subjects for the visualization and analysis of the electrical activity of the brain by fusing a variety of EEG and/or Magnetoencephalographic (MEG) data, with Magnetic Resonance (MRI), functional Magnetic Resonance (fMRI), Computer Tomography (CT), Positron Emission Tomography (PET) and/or Single Photon Emission Computed Tomography (SPECT) images.
Technological Characteristics:	The Neurosoft CURRY® Multimodal Neuroimaging Software has similar technological characteristics and indications for use, and is therefore substantially equivalent to the SAM Technology's "IMAGE VUE EEG."
Safety and Effectiveness Comparison to Predicate:	The results of bench and user testing indicate that the software is safe and effective as the predicate software.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 5 2001

Mr. David B. Jones
Regulatory Affairs/Quality Assurance Manager
Neurosoft, Inc.
5700 Cromo Drive
Suite 100
El Paso, Texas 79912

Re: K001781
Trade Name: Neurosoft CURRY® Multimodal Neuroimaging Software
Regulatory Class: II
Product Code: GWQ
Dated: October 27, 2000
Received: November 7, 2000

Dear Mr. Jones:

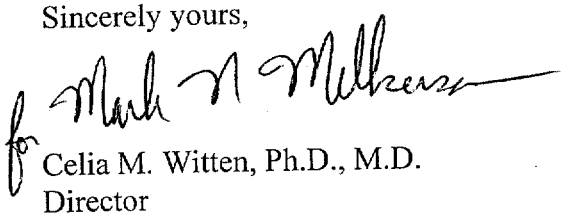
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IV. Statement of Indications for Use

Applicant: Neurosoft, Inc.
45150 Business Court, Suite 100
Sterling, VA 20166
Phone: (703) 904-9600
Fax: (703) 904-7870

510(k) Number: K001781

Device Name: Neurosoft **CURRY® Multimodal Neuroimaging Software**

Indications For Use: The Neurosoft **CURRY® Multimodal Neuroimaging Software** is intended for use by qualified/trained EEG technologists and/or physicians on both adult and pediatric subjects for the visualization and analysis of the electrical activity of the brain by fusing a variety of EEG and/or Magnetoencephalographic (MEG) data, with Magnetic Resonance (MRI), functional Magnetic Resonance (fMRI), Computer Tomography (CT), Positron Emission Tomography (PET) and/or Single Photon Emission Computed Tomography (SPECT) images.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001781

Prescription Use_____ or Over-the-Counter_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)